DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
WASHINGTON, D.C. 20390

IN REPLY REFER TO
BUMED-742:CFT
File: 6470/
USS SANCTUARY
Serial: 1251
1 December 1966

From: Chief, Bureau of Medicine and Surgery
To: Director, Division of Licensing and Regulation
U. S. Atomic Energy Commission
Washington, D. C. 20545

Subj: USS SANCTUARY (AH-17) Application for Radioisotope License to employ I^{131} and I^{125} as RISA for blood volume determination

Encl: (1) Subject application

1. Forwarded, recommending approval.

2. USS SANCTUARY (AH-17) is to be considered licensee rather than (b) (6), MC, USN. This change has been effected.

3. The technicians are not considered individual users. This change has been effected.

(b) (6)

90757

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UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 38-R080

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME

LCDR (b) (6)
Naval Hospital USS SANCTUARY
C/O F.P.O. San Francisco, Calif.

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a). Include ZIP Code.)

(b) (6)
CTUARY (AH-17)
c/o F.P.O. San Francsico, Calif. 96601

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER — (YES) NO

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER — (YES) NO

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary):

Radio iodinated Serum Albumin for Standard Blood Volume determination.

(b) CHEMICAL FORM ADMINISTERED:

I 131 or I 125 as iodinated serum albumin

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

See page 2

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE
(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER — YES (NO)

(2) ON FILE WITH THE ISOTOPES BRANCH
REFER TO APPLICATION NO _____ CIRCLE ANSWER — YES (NO)

5. PROPOSED DOSAGE SCHEDULE
(a) In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

Standard pre-packaged individual dose syringes(disposable)- 5 to 10 microcuries, except I 125.

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER — YES (NO)

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES:

See item 5

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7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. Individual license application CIRCLE ANSWER — YES (NO)

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE. Not applicable CIRCLE ANSWER — YES NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED. CIRCLE ANSWER — YES NO

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

This page may be used for providing additional information. Please cross reference to specific items.

Equipment-- Volemetron (Ames)

Facilities--A stainless steel work surface in Urinalysis will be provided for isotope work. The area will be surveyed after each use.

Radiation Protection Program

1) Only qualified technicians will handle isotopes under the direct supervision of the licensee.
2) Individual dose pre-packaged syringes will minimize risk of contamination.
3) Isotopes will be stored in a locked strong box in the laboratory refrigerator.
4) Appropriate warning signs will be provided.
5) The storage area will be monitored monthly.
6) Radioactive wastes, liquid and solid, will be placed in plastic bags and will be sealed in a metal container until decay permits disposal at sea.
7) See items 10, 11, 12 Form AEC 313.

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(11/63)
PAGE 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Back of page may be used for comments.

9. NAME AND ADDRESS OF APPLICANT PHYSICIAN *(Include ZIP Code.)*

(b) (6) [redacted]
LCDR MC USN

Pathology Department
U. S. Naval Hospital
Jacksonville, Florida

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 9 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
I 131	Diagnosis of thyroid function	67	67
	Dilution studies	2	2
	Excretion studies		
	Brain tumor localization	1	1
	Scanning studies IHSA	15	15
	Treatment of hyperthyroidism		
	Treatment of cardiac conditions		
	Treatment of thyroid carcinoma		
P-32 Soluble	Treatment of polycythemia		
	Treatment of leukemia		
	Treatment of bone metastases	1	1
	Tumor localization		
	Intracavitary treatment		
	Interstitial treatment		
Au-198	Intracavitary treatment		
	Interstitial treatment		
	Scanning studies		
Cr 51	Blood determinations		
	Scanning studies		
Co-58 or Co-60	Diagnosis of pernicious anemia		
Co 60	Interstitial treatment		
I 192	Intracavitary treatment		
Co 60 or Cs 137	Teletherapy treatment		
	Total Blood Volume	42	42
	Red Cell Survival	3	3
Sr 90	Treatment of superficial diseases of the eye		
Other Isotopes Use back of page	In Vivo Counting	3	3
	Co-57 and Co-60 Schilling Test	3	3
	Hg-203 Renal Scan	12	12

(Continued on Reverse Side)

Key to Columns (C) and (D) above

1 Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

11 DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING 3 months

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF Graduated from full-time Medical Officers Course (9-17-62 to 12-7-62) (b) (6) [redacted] SN

AT U.S. Naval Hospital
Bethesda, Maryland
(Institution) Name and Address

19-2891-5
(Byproduct Material License Number)

90757
(Signature of Preceptor)

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

This page may be used for providing additional information.

	(C)	(D)
I-131 Diagnostic Studies - Continued		
I-131 Hipputope, Renogram	25	25
I-131 Triolein Fat Metabolism	1	1
I-131 Oleic Acid, Fat Metabolism	1	1
I-131 HSA, Placentogram	4	4
Other Isotopes; Diagnostic Studies - Continued		
Au-198 Liver Scan	19	19
Fe-59 Iron Utilization	1	1
Fe-59 Plasma Iron Disappearance	1	1
Fe-59 Invivo Counting	1	1

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TRAINING AND EXPE[illegible]CE OF EACH INDIVIDUAL NAMED IN ITEM 4 *(Use supplemental sheets if necessary)*

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	Drs. (b) (6) and (b) (6)	3 months	Yes No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments	(b) (6) and (b) (6)	6 months	Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity			Yes No	Yes No
d. Biological effects of radiation	All above named received traning at USNH Bethesda, Md.		Yes No	Yes No

9. EXPERIENCE WITH RADIATION. *(Actual use of radioisotopes or equivalent experience.)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I131 RISA	5-10 micro curies /dose	US Naval Hospital Jacksonville, Fla.	One Year	Blood Volume

10. RADIATION DETECTION INSTRUMENTS. *(Use supplemental sheets if necessary.)*

TYPE OF INSTRUMENTS *(Include make and model number of each)*	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE *(mr/hr)*	WINDOW THICKNESS *(mg/cm²)*	USE *(Monitoring, surveying, measuring)*
AN-PDR-27	8	Gamma, Beta	Up to 500 mr/hr.		Surveying working areas measuring waste for disposal.

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE.

Maintained by Damage Control Division of the ship.

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED. *(For film badges, specify method of calibrating and processing, or name of supplier.)*

Film badges provided to all users by Radiology Service. Processed monthly in accordence with BuMed instructions.

acc

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. *(Circle answer)* Yes No

See Form AEC-313a

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

See Form AEC-313a

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

See Form AEC-313a

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

Date 22 November 1966

(b) (6)

[illegible]inistrative Officer

Naval Hospital USS SANCTUARY (AH17)

Title of certifying official

WARNING.—18 U. S. C., Section 1001, Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

* U.S. GOVERNMENT PRINTING OFFICE : 1964 O—745-382

Form AEC 313
(8 64)
10 CFR 30

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved
Budget Bureau No. 38-R027

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application or an application for renewal of a license. Information contained in previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided references are clear and specific. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Isotopes Branch, Division of Materials Licensing. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Part 20.

1. (a) NAME AND STREET ADDRESS OF APPLICANT. *(Institution, firm, hospital person, etc. Include ZIP Code.)*

(b) (6) [redacted]
Clinical Laboratory
USS SANCTUARY (AH17)
FPO San Francisco 96601

(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. *(If different from 1(a). Include ZIP Code.)*

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Clinical Laboratory

3. PREVIOUS LICENSE NUMBER(S). *(If this is an application for renewal of a license, please indicate and give number.)*

Previously listed as a user on institutional license 9-11026-1 U. S. Naval Hospital, Jacksonville, Fla.

4. INDIVIDUAL USER(S). *(Name and title of individual(s) who will use or diredly supervise use of byproduct material. Give training and experience in Items 8 and 9.)*

(b) (6) [redacted]

5. RADIATION PROTECTION OFFICER. *(Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.)*

LT (b) (6) [redacted], MC, USN
Radiology Service
NAVAL HSOPITAL
USS SANCTUARY (AH17)

6. (a) BYPRODUCT MATERIAL. *(Elements and mass number of each.)*

(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME *(If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.)*

Iodine 131	Iodinated Human Serum Albumin	1 millicurie
Iodine 125	Iodinated Human Serum Albumin	1 millicurie

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. *(If byproduct material is for "human use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)*

See Form AEC-313a

90757

(Continued on reverse side)

USS SANCTUARY (AH-17)
FLEET POST OFFICE
SAN FRANCISCO, CALIFORNIA 96601

0422

H:WPA:jws
5000
10 Feb 1969

Richard E. CUNNINGHAM
Chief Isotopes Branch
Division of Materials Licensing
U.S. Atomic Energy Commission
Washington, D.C. 20545

Dear Mr. CUNNINGHAM:

Our failure to submit renewal application for by product material (Radioisotope) license is due to some difficulties encountered resulting from our frequent change of personnel. We intend to apply for renewal and are presently in the process of re-evaluation of our isotope program. No procedures utilizing radioisotopes have been performed since expiration of previous license on 31 Dec 1968, and in accordance with regulations, none will be performed until final action has been taken on our application. The application will be forwarded as soon as our re-evaluation is complete which should be only a matter of a few days.

Sincerely

(b) (6)

CDR MSC USN
Administrative Officer
By direction

Nothing in 4-2-69